

Lezdey et al is also irrelevant to the present invention for reason stated in the previous amendment which is herein incorporated by reference.

Under the Examiner's theory one would treat burns in combination with Lezdey et al with an extract of olive oil. However, there is no relationship between burns and diaper rash.

Henley teach use of electrokinetic delivery of cromolyn to treat a fungus (diaper rash). Applicant is treating inflammation resulting from bacteria and urine with cromolyn in a pharmaceutically acceptable vehicle.

One in the art would not electrokinetically treat burns or diaper rash. The primary reason is that both burns and diaper rash have toxins which would enter the skin and penetrate into the blood. With diaper rash and decubitus ulcers the irritation is primarily on the epidermis. Cyclodextrin is primarily used to penetrate the rash on the surface.

Consequently, the combination of Lezdey et al, Perricone and Henley et al do not teach or suggest treatment of bacterial diaper rash or decubitus ulcers.

The Examiner fails to understand the article of Gray as having pertinence to the present invention. The Examiner mentions babies having prenatal bodily hair which falls off after birth. However, prenatal babies do not get diaper rash. Also, the hair of newborn is on the head where there are sebaceous glands. Babies do not get diaper rash on their heads.

Consequently the Gray article does not support the Examiner's position.

As previously discussed, Weiner et al is not pertinent to the present invention. Weiner et al relates to the delivery of a weak acid or base. Cromolyn is neither.

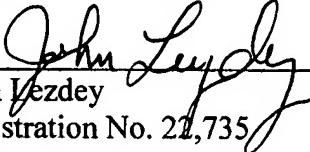
Moreover, the reference states that there is a reaction between cyclodextrin and minoxidil. In applicant's invention there is no chemical reaction. Also, the reference states that there is good penetration through hair follicles. As noted in the Gray reference, there are no hairs where there would be diaper rash on new born babies. Even if there were hairs the penetration through hairs would not solve the problem of a rash on top of the epidermis.

In conclusion, not one of the references cited have a bearing on the invention as presently claimed. The examiner is employing hindsight using the present invention as a template and has cited references which do not relate to treating decubitus ulcers and bacterial diaper rash with cromolyn. The Examiner admits that Lezdey et al and Perricone do not relate to the present invention. Henley et al teaches electrokinetic absorption which does not solve a problem relating to drugs in a pharmaceutical carrier. Moreover, Henley et al relates to fungal diaper rash but cromolyn is not an anti-fungal agent. Henley has to of been referencing an imadazole that is anti-fungal.

Gray obviously has no pertinence to the invention.

Reconsideration and favorable action are earnestly solicited.

Respectfully submitted,


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The World of Hair

an on-line reference by Dr. John Gray,
provided by the P&G Hair Care Research Center.
For more beauty science, please visit
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PANTENE PROV

For tests, tips, and
hair health advice,
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Page 7 -- VARIATIONS IN HUMAN



Variations in human hair

Human hair varies enormously. Different people have hair that differs in color, in length, in diameter, and in its distribution on the body. As we shall see later, some of these factors are influenced by the person's racial type, and some by his or her age.

Types of hair

Three types of hair grow on the human body.

Lanugo hair

This is the hair that develops on an unborn baby. It begins to grow about three months after the baby's conception. The hairs are fine and soft, and they grow all over the baby's body. They all grow at the same rate, so the hairs are the same length.

Some prematurely born babies are still covered with these downy hairs. Normally they are shed about four weeks before the baby is due to be born.

Vellus hairs

Vellus hairs are short hairs, only a centimetre or two long, and contain little or no pigment. The follicles that produce them do not have

oil glands (often called sebaceous glands), and never produce any other kind of hairs.

Terminal hairs

Terminal hairs are the long hairs that grow on the head and in many people on the body, arms and legs too. They are produced by follicles with sebaceous glands. In people who have inherited a tendency to baldness the hairs in these follicles gradually become thinner and shorter until they look like vellus hairs.

Variation with age

Childhood

A newly born full-term baby has two types of hair. Terminal hairs grow on the scalp and eyebrows, but nowhere else. All the rest of the hair is vellus hair.

As the baby grows, the hair on the head grows too. There are two periods during which hair grows rapidly on the scalp. In both, the hair growth begins at the forehead and then extends to the back of the neck. When the baby is two or three months old, the first hairs may be shed naturally over an area on the back of the head. This is often mistakenly thought to be due to head rubbing; hairs broken by rubbing may, however, be found on other parts of the head as well.



Naturally occurring hair loss, which begins at age 8-12 weeks



Mosaic patterns starting to develop; the beginning of hair streaks can also be seen



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